

8959-51

5/28/2014

1/10



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

MAY 28 2014

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

Patti Golick
Sr. Commercial Regulatory Services Associate
Applied Biochemists
c/o Lonza Inc.
90 Boroline Road
Allendale, NJ 07401

Subject: Clearigate
EPA Registration No.: 8959-51
Application Date: May 6, 2014
Receipt Date: May 7, 2014

Dear Ms. Carswell:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c) 9.

Proposed Notification:

Request to revise the current label to reflect a series of changes: add note to reviewer, insert Spanish language, and correct typos.

General Comment:

Based on a review of the material submitted, the following comment applies: your notification to modify the label to incorporate the revisions listed above are acceptable and a copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at campbell.jacqueline@epa.gov or Terria Northern by telephone at (703) 347-0265 or by e-mail at northern.terria@epa.gov during the hours of 8:00am to 4:00pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink, appearing to read "Jacqueline Hardy".

Jacqueline Hardy
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

EPA Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
	United States	

Application for Pesticide - Section 1

1. Company/Product Number 8959-51	2. EPA Product Manager Jacqueline Hardy	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Clearigate	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Applied Biochemists c/o Lonza Inc. 90 Boroline Road Allendale, NJ 07401	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name	
<input type="checkbox"/> Check if this is a new address		

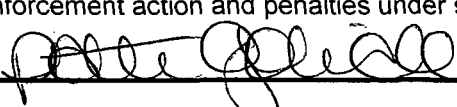
Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Not Subject to PRIA**Label Notification to add Note to Reviewer, Spanish language, correct typos. Please see cover letter for details.**

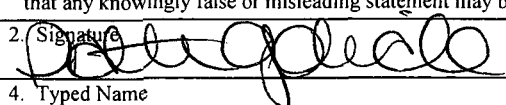
This notification is consistent with the provisions of PR-Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Signature: Date: 5/6/14

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No *Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per container	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) Bag		
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 40 lbs.		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Stenciled					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Patti Golick	Title Sr. Regulatory Services Associate	Telephone No. (Include Area Code) 201-316-9243
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Sr. Regulatory Services Associate	
4. Typed Name Patti Golick	5. Date 05-06-14	

Via FedEx

Ms. Jacqueline Hardy (PM-34)
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2227 S. Crystal Drive
Arlington, VA 22202

Lonza Inc
Allendale
90 Boroline Road
Allendale, NJ 07401, USA

Patti Golick
Lonza Life Science Ingredients
Regulatory Assurance

Tel 201-316-9293
Fax 201-696-3463
patti.golick@lonza.com

May 6, 2014

**SUBJECT: Clearigate EPA Reg. No. 8959-51
Application for Label Notification**

Dear Ms. Hardy:

I am submitting an application to make the following changes to the abovementioned product label:

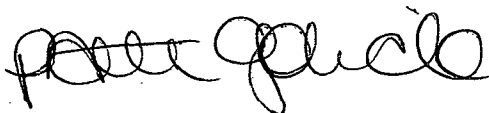
- Page 1:
 - Add Note to Reviewer
 - Changed "Other" to "Inert"
 - Added the Spanish signal word PELIGRO
 - Revised the statement See Additional Precaution and Directions for Use Inside Booklet
- Page 3: Added the following Spanish statement along with English translation
 - *Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. [If you do not understand the label, find someone to explain it to you in detail.]*
- Page 4:
 - Corrected two application rates under Najas spp. (Naid) and Pondweeds

Please find the enclosed documents in support of this notification:

- Application for Notification;
- Certification with Respect to Label Integrity;
- CD with Label;
- One copy of the proposed label with changes highlighted.

If you have any questions or need any additional information, please feel free to contact me at 201-316-9293.

Sincerely,
Lonza Inc.



Patti Golick
Sr. Commercial Regulatory Services Associate

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Note to reviewer:

[Items in brackets [AAA] are optional and may/may not be included on final label]

{Items in braces {AAA} are for information purposes and will not appear on final label}

CLEARIGATE

FOR USE IN CROP AND NON-CROP IRRIGATION CONVEYANCE SYSTEMS: DITCHES, CANALS AND LATERALS; POTABLE WATER RESERVOIRS; LAKES; FARM, FISH, GOLF COURSE, INDUSTRIAL AND SWIMMING PONDS

ACTIVE INGREDIENT:

COPPER AS ELEMENTAL 3.825%

INERT INGREDIENTS 96.175%

TOTAL 100.00%

From mixed Copper Ethanolamines in an Emulsified Formulation

Clearigate CONTAINS 0.31 LBS. OF COPPER PER GALLON

KEEP OUT OF REACH OF CHILDREN DANGER [PELIGRO]

See Additional Precautions and Directions for Use Inside Booklet

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes. Then continue rinsing. Call Poison Control Center or doctor for treatment advice.

IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call Poison Control Center or doctor for treatment advice.

IF SWALLOWED: Call Poison Control Center or doctor immediately for treatment advice.

Have person sip a glass of water if able to swallow.

Do not induce vomiting unless told to by a Poison Control Center or doctor.

IF INHALED: Move person to fresh air.

If person is not breathing call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.

Call Poison Control Center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. If a medical emergency arises contact Arch Chemicals Emergency Action Network in the US call 1-800-654-6911 or outside the US call 423-780-2970. For help with a spill, leak, fire or exposure involving this material call CHEMTREC 1-800-424-9300.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

Measures against circulatory shock as well as oxygen and measures to support breathing manually or mechanically may be needed. If persistent, convulsions may be controlled by the cautious intravenous injection of a short-acting barbiturate drug.

EPA Reg. No. 8959-51

EPA Est. No. 42291-GA-1

Pat.# 5,407,899

Net Contents (insert container size here)

MANUFACTURED BY:

Applied Biochemists

GERMANTOWN, WISCONSIN 53022

1-800-558-5106

www.appliedbiochemists.com

Clearigate

EPA Reg. No. 8959-51

EPA DRAFT 2014-05-05

Note to reviewer:

[Items in brackets [AAA] are optional and may/may not be included on final label]

{Items in braces {AAA} are for information purposes and will not appear on final label}

GENERAL GUIDELINES:

Clearigate is a chelated copper formulation containing an emulsified surfactant / penetrant for highly effective control of coarse (thick cell-walled) filamentous algae, muscilaginous (colonial) planktonic algae, Chara and a variety of emergent, floating and submerged aquatic plants. Vegetation controlled includes: Cladophora, Pithophora, Lyngbya, Microcystis, Hydrilla, pondweeds, water milfoil, naiad and other species having a sensitivity to copper absorption in conjunction with a penetrant.

FOR OPTIMUM EFFECTIVENESS:

Apply Clearigate early in the day under bright or sunny conditions when water temperatures are at least 60°F (15.5°C).

Apply when growth first begins to appear or create a nuisance.

Apply in a manner which will ensure even distribution of product within treatment area.

Repeat application, as needed, if regrowth begins to appear and seasonal control is desired.

Allow one to two weeks between consecutive treatments.

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.

[If you do not understand the label, find someone to explain it to you in detail.]

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Read entire label. Use strictly in accordance with precautionary statements and directions and with applicable State and Federal Regulations.

STATIC WATER TREATMENT

SURFACE SPRAY /INJECTION APPLICATION

For effective control, proper chemical concentration contact should be maintained for a minimum of three hours. Application rates in the chart below are based upon static or minimum flow situations in lakes, ponds, reservoirs and inactive irrigation conveyance systems or drainage systems. Where significant inflow occurs (greater than 10% of total water volume in 24 hours), it is recommended that flow be stopped for 24 hours during and following treatment. If this is not possible, treat inflowing water in accordance with Flowing Water Treatment instructions.

Due to the potential toxicity to fish at dosages in excess of 0.5 ppm copper, the use of Clearigate above this level is suggested only by experienced applicators. In areas where fish are not present or where some fish kill is not objectionable, total volume treatments can be made. In all other areas, treatments above 0.5 ppm copper should not exceed 1/3 to 1/2 of the entire water body, allowing one to two weeks between consecutive treatments.

Select dosage rate based upon species/type of plants being controlled. Choose a dilution which will allow relatively even application throughout the intended treatment area with the type of equipment being used. Avoid drift by using coarse spray droplets, applying close to the water surface and/or injecting solution below the water surface through submersed hoses for treatment of submerged growth.

Aquatic Vegetation	Dosage	Rates	Dilution	Treatment Comments
Type or Species	PPM	Gallons	%Spray	
	Copper	Per Acre-Foot	Solution V/V	
ALGAE				
Planktonic	0.1-0.5	0.9 - 4.4	1.5%-5%	Apply lower dosage rates on light infestations. Use higher rates on heavy blooms and where algae masses are
Filamentous	0.2-0.6	1.8 - 5.3	5%-10%	Apply lower dosage rates on early season, light infestations or treatment of regrowth. Apply higher rates on surface mats and coarse species such
Chara/Nitella	0.4-0.8	3.6 - 7.1	10%-15%	Apply lower dosage rates on new infestations or early season growth. Apply higher rates on older, established calcified plants. Apply as close to top of
SUBMERGED PLANTS				
<i>Egeria densa</i> (Brazilian Elodea)	0.6-1.0	5.4 - 8.7	10% -20%	Apply lower dose on early season, low density growth. Apply higher rates in thicker stands of plants. Product should be applied as close to the top of the plants as possible. Underwater injection is
<i>Elodea canadensis</i>	0.8-1.0	7.1- 8.7	10%-20%	
<i>Hydrilla verticillate</i>	0.4-1.0	3.6 - 8.7	10%-20%	
<i>Myriophyllum</i> spp. (Water Milfoil)	0.8-1.0	7.1- 8.7	10%-20%	
<i>Najas</i> spp. (Naiad)	0.5-1.0	4.4 - 8.7	10%-20%	
<i>Potamogeton</i> spp. (Pondweeds)	0.5-1.0	4.4 - 8.7	10% - 20%	
FLOATING PLANTS		Gallons per Surface Acre		
<i>Lemna</i> spp. (Duckweed)		4.4 - 8.7	20%-25%	Apply lower rates to shallow (less than 1ft.) infestations. Use higher rates for large infestations in deeper water (1foot or greater). Use a fine spray and wet plants thoroughly. Do not disturb
<i>Eichornia crassipes</i> (Water Hyacinth)		4.4 - 8.7	20%-25%	

FLOWING WATER TREATMENT DRIP SYSTEM/METERING PUMP APPLICATION

Effective aquatic plant control in flowing water (canals, ditches, laterals, etc.) is dependent upon maintaining suitable contact time with sufficient chemical concentrations. Other factors to consider include: type of growth present, degree of infestation, water temperature and weather conditions during and following treatment. Fish may be killed at dosages in excess of 0.5 ppm copper in flowing water. Use dosages over 0.5 ppm only in areas where some fish kill is not objectionable or where fish have access to downstream avoidance of these concentration levels.

1. Prior to treatment, it is important to accurately determine water flow rates. In the absence of weirs, orifices or similar devices which provide accurate water flow measurements, volume of flow may be estimated via the following formula:

$$\text{Average Width (ft.)} \times \text{Average Depth (ft.)} \times \text{Velocity}^*(\text{ft/sec}) \times 0.9 = \text{Cubic Feet per Second (CFS)}$$

*Velocity is the time it takes a floating object to travel a given distance. Dividing the distance traveled (ft) by the time (seconds) will yield velocity (ft/sec). Repeat measurement at least 3 times at the intended application site and use the average of these measurements.

2. Calculate volume of ditch, canal, lateral or receiving pond in cubic feet based upon water levels at the time of treatment by using the following formula:

$$\text{Length (ft)} \times \text{Average width (ft)} \times \text{Average depth (ft)} = \text{Cubic Feet of Water}$$

3. Calculate turnover time (the amount of time it takes for the water in the system to be replaced by new water). Convert to hours using the following formula:

$$\frac{\text{Canal Volume (ft}^3\text{)}}{\text{Flow Rate (CFS)}} \div 3600 = \text{Turnover Time (hrs.)}$$

4. Select dosage rate from the chart below and calculate total Clearigate requirements by using the formula following the chart.

AQUATIC VEGETATION TYPE	PPM COPPER	DOSAGE RATE QT. PER CFS/HOUR*
PLANKTONIC ALGAE	0.1 - 0.5	0.3-1.4
FILAMENTOUS ALGAE	0.2 - 0.6	0.6 - 1.7
CHARA/NITELLA	0.4 - 0.8	1.2 - 2.3
SUBMERGED WEEDS	0.5 - 1.0	1.4 - 2.8

NOTE: Use higher dosage range in cooler water (60°F- 70°F), under conditions of heavy growth and/or on matured plant growth. Lower dosage ranges may be used on maintenance control treatments, young plants and/or under minimal growth conditions in warmer waters (>70°F).

$$\text{CLEARIGATE Required (qts)} = \text{Dosage Rate (qt/CFS/hr)} \times \text{Flow Rate (CFS)} \times \frac{\text{Turnover Time (hrs)*}}{1}$$

NOTE: If turnover time is less than 3 hrs, substitute 3 hrs. into this calculation.

5. For ditches, canals and laterals determine the number of drip/metering application sites required (based upon turnover time) by referring to the chart below:

TURNOVER TIME (Hrs) NUMBER OF DRIP/METERING SITES	
Less than 4.5	1
4.6 - 7.5	2
7.6 - 10.5	3
10.6-13.5	4
13.6 - 16.5	5

Sewage treatment ponds and other sites where water is stored for a calculated retention time and are fed by a single input source will require a single dripper/metering system. Inflowing water should be treated at the appropriate dosage rate from the chart in #4 for the duration of the entire turnover time calculated in #3.

6. Calculate distance between drip/metering sites by using the following formula:

$$\frac{\text{Canal/Ditch/Lateral Length (ft)}}{\text{No. of Drip/Metering Sites}} = \text{Distance Between Drip/Metering Systems (ft)}$$

7. Calculate amount of CLEARIGATE required per drip/metering site by using the following formula:

$$\text{Total CLEARIGATE Required (qts)} = \text{CLEARIGATE Required Per Site (qts.)} \times \text{No. of Drip/Metering Sites}$$

8. Calculate drip/metering duration per site by using the following formula:

$$\frac{\text{CLEARIGATE Required Per Site (qts)}}{\text{Dosage Rate (qt/CFS/hr)} \times \text{Flow Rate (CFS)}} = \text{Drip Metering Duration (hrs) Per Site}$$

9. Calculate Drip/Metering Rate by using the following formula to convert to oz./min or ml/min.

$$\text{Flow Rate (CFS)} \times \text{Drip Rate (qt/CFS/hr)} \times 0.533^* = \text{Drip Rate (oz/min.)}$$

NOTE: 0.533 is a constant used to convert qt/hr to oz/min

METRIC CONVERSION: Drip Rate (oz/min) x 29.57 = Drip Rate (ml/min)

Calibrate drip system, metering pump or similar dosage device to establish output rate determined in Step No. 9. This can be done using a watch with a second hand and a calibrated measuring cup, graduated cylinder or similar vessel.

If possible, calibrate all drip/metering devices prior to beginning actual treatment. Turn them on as simultaneously as possible, beginning with the device furthest upstream.

Begin with only the amount of product required at each site or record your start-up time and shut down drip/metering systems after the drip/metering duration time period determined in Step No. 8.

Remove containers from application sites following treatment. Triple rinse application equipment. Dispose of empty containers in accordance with container disposal instructions on this label. Partially used containers should be resealed with original closures and stored in accordance with storage instructions on this label.

STORAGE & DISPOSAL:

Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited.

PESTICIDE STORAGE: Keep container closed when not in use. Keep pesticide in original container. Do not put concentrate or dilute into food or drink containers. Do not reuse or refill container. Do not contaminate feed, feedstuffs, or drinking water. Do not store or transport near feed or food. Store at temperatures above 32°F. Do not store near heat or flame.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional office for guidance.

(For <5gallon non-refillable containers only):

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse container. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning if available or puncture and dispose of in approved landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. Consult Federal, State or local authorities for approved alternative procedures.

(For >5gallon non-refillable containers only):

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse container. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ with water and recap. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand container on its end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning if available or puncture and dispose of in approved landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. Consult Federal, State or local authorities for approved alternative procedures.

(For 275Gallon refillable container only):

CONTAINER DISPOSAL: Refillable container. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill container about 10 percent full with water. Agitate vigorously or recirculate water with pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat rinsing procedure two more times. Then offer for recycling or reconditioning if available or puncture and dispose of in approved landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. Consult Federal, State or local authorities for approved alternative procedures.

Warranty

To the extent consistent with applicable law neither the manufacturer nor the seller makes any warranty, expressed or implied concerning the use of this product other than indicated on the label.

To the extent consistent with applicable law buyer assumes risk of use of this material when such use is contrary to label instructions. Read and follow the label directions.